YOUNG CONAWAY STARGATT & TAYLOR, LLP
Attorneys at Law

WILMINGTON
RODNEY SQUARE

NEW YORK
ROCKEFELLER CENTER

March 11, 2019

BY E-FILE AND HAND DELIVERY

The Honorable Colm F. Connolly
United States District Court of Delaware
844 North King Street
Wilmington, DE 19801

REDACTED - PUBLIC VERSION

Re: *Genentech, Inc. v. Amgen Inc.*, C.A. No. 17-1407-CFC (Consolidated)

Defendant Amgen Inc. opposes the relief requested in Plaintiffs' March 8, 2019 letter brief.

I. The Court should deny Plaintiffs' request to modify the Protective Order to permit a separate lawsuit against Amgen's manufacture of Mvasi™ at [redacted] *for at least three reasons. First*, a separate lawsuit against Mvasi™ is an attempted end run around the present action. The allegations in Plaintiffs' "new" complaint against Mvasi™ are duplicative of those here, with one important difference—Plaintiffs assert two new patents[1] that they failed to identify by the August 31, 2018 patent narrowing deadline. D.I. 201, at ¶8. If Plaintiffs wished to assert them, the Scheduling Order (subject to the strictures of the BPCIA) provided the proper mechanism: "After the August 31, 2018 deadline, Plaintiffs shall be permitted to select as many as two (2) additional patents upon a showing of good cause." *Id.* The Court should not permit Plaintiffs to evade Fed. R. Civ. P. 15, the BPCIA, or the "good cause" requirement to assert new patents by filing a new complaint.

Second, a new suit against Amgen's [redacted] Mvasi™ is redundant and wasteful because such activities are already a focus of this case. Over nearly the last year, Plaintiffs relentlessly sought (and received, largely before the patent narrowing deadline) discovery on [redacted] including: (i) documents responsive to June 2018 requests (Ex. 1, at RFP Nos. 100-107); (ii) testimony responsive to July 2018 30(b)(6) deposition topics (Ex, 2, Topics 43-48); (iii) responses to a November 2018 interrogatory (*e.g.*, Ex. 3, at 4-6); and (iv) [redacted] product samples ordered by the Court, on which Plaintiffs relied to narrow the claims (Ex. 4, at 2). Amgen has provided everything Plaintiffs need to litigate [redacted] under the current case schedule.

Third, Amgen's [redacted]—on which Plaintiffs rely to support their request—does not permit Plaintiffs to file a new lawsuit against Amgen arising under the BPCIA. Ex. 5, at 1.[2]

[redacted]

[2] Plaintiffs' brief hides a key purpose of their request—to use the new suit as pretext to pressure Amgen to not launch Mvasi™, by also alleging infringement against an unrelated Amgen product, [redacted] D.I. 291, Ex. 2, at ¶¶233-242. Use of Amgen "Confidential" information for this purpose violates the Protective Order, and there is no legitimate reason (and Plaintiffs provide none) to modify the Protective Order to allow this conduct. *Phillips Petroleum Co. v.*

II. Amgen's ex-U.S. activities are irrelevant. Amgen has produced extensive discovery regarding its U.S. activities involving Mvasi™, including its manufacture of the product and other activities that occurred in the U.S. (if any). Plaintiffs' request for Amgen's "plans" overseas is merely an attempt to obtain Amgen's highly confidential [redacted] to gain a competitive advantage and pursue litigation in different countries.

First, Plaintiffs incorrectly argue that Amgen's alleged [redacted] is "infringing" (D.I. 291, at 2). In fact, it is not an infringing act merely to [redacted][4] and Amgen has already produced discovery concerning the activities that Plaintiffs (wrongly) accuse of infringement—manufacture of Mvasi™ in the U.S.

Second, Plaintiffs are not entitled to discovery regarding the "uses of Mvasi to secure foreign regulatory approval" in excess of what Amgen has agreed to produce. Although Amgen disputes Plaintiffs' characterization of the documents cited in their brief, they admittedly already have information regarding Amgen's U.S. activities involving Mvasi™. Amgen has also agreed to produce (if they exist) documents showing [redacted]. Such documents reasonably provide the information Plaintiffs seek. Additional discovery, including foreign regulatory submissions, is irrelevant and disproportionate to the needs of the case. *Abbvie Inc. et al. v. Boehringer Ingelheim Int'l. GMBH*, No. 17-cv-1065, D.I. 428, at 12-13 (D. Del. Feb. 25, 2019) (declining to compel more discovery on "stockpiling" in light of prior production of "detailed information about all the batches of biosimilar drug it has manufactured.") (Ex. 6).

III. The Court should not allow a fishing expedition into unrelated Amgen products and processes. Plaintiffs improperly argue that they "need" discovery regarding unrelated

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Rexene Prods. Co., 158 F.R.D. 43, 46 (D. Del. 1994) ("the burden of demonstrating that an agreed protective order should be modified is on the moving party"); *Biovail Labs., Inc. v. Anchen Pharm., Inc.*, 463 F. Supp. 2d 1073, 1082-83 (C.D. Cal. 2006) (declining to modify protective order because disclosing "generic ANDA and amendments thereto" to competitor "would be extremely damaging to Anchen's interests.").

[3] As discussed at length at the October 10, 2018 hearing, Genentech used information uncovered in this case as a pretext to [redacted]. Plaintiffs also abused the discovery process by using information from this case to attempt to accuse Amgen's unrelated [redacted] product in its proposed Second Amended Complaint. D.I. 263, at 2.

[4] *See Chartex Intern. PLC v. M.D. Personal Prods. Corp.*, 5 F.3d 1505 at *3 (Fed. Cir. 1993) ("overseas business arrangements do not constitute infringement" because "[m]aking arrangements to have a device manufactured overseas or making arrangements to have it imported into a foreign country is neither an infringing 'making,' 'using,' or 'selling' of the invention within the [U.S.]"); H.R. Rep. No. 98-857(I), at 45 (1984) (The purpose of §"271(e)(1) and (2) is to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement."). As such, Plaintiffs are incorrect that "[a]ctivities not required for U.S. approval are not protected by the . . . 'safe harbor . . .'" and are "actual infringement . . . ." D.I. 291, at 2.

Amgen products and manufacturing processes "to understand [redacted] D.I. 291 at 3.

First, Plaintiffs have no "need" to know [redacted]. This case is to resolve disputes related to Mvasi™, and Amgen has produced extensive discovery regarding the composition of Mvasi™ and its manufacturing process, including how the product was developed. Information about other Amgen products or processes will not move the ball forward in resolving any relevant issue in this case.

Second, Plaintiffs' relevance justification falls apart upon a cursory reading of the request Plaintiffs ask to enforce, because it is untethered to the information Plaintiffs allegedly want. Plaintiffs' request for "representative copies of functional specifications, process validation reports, and/or batch records showing the processes by which Amgen's other biologic products are manufactured" would have Amgen produce detailed records regarding *every* Amgen product, without reference to Mvasi™ or the asserted patents. The request is vastly overbroad, irrelevant, and disproportionate to the needs of this case, and enforcing it would only advance a litigation strategy as an in terrorem gambit to discourage competition with regard to Genentech's bevacizumab product. *Tessera Inc. v. Sony Elecs., Inc.*, 2012 WL 13035109, at *2-*3 (D.N.J. Aug. 8, 2012) (declining to compel "all of [defendant's] . . . semiconductor products" because request was "overly broad" by seeking "information beyond the patents-in-suit" and "unduly burdensome," by seeking "numerous products . . . not alleged").

IV. The Court should not compel discovery regarding the development of an Amgen [redacted] divorced from its application to Mvasi™. Plaintiffs improperly seek "any documents" regarding [redacted] how Amgen used [redacted] for products *other than Mvasi™*. D.I. 291, Appendix, at RFP Nos. 129-131. In response, Amgen produced [redacted], documents showing how Amgen developed [redacted] for Mvasi™, and a 30(b)(6) witness on this subject.

Plaintiffs are entitled to nothing more—the development of [redacted] for other products, is irrelevant and disproportionate to the needs of the case. Plaintiffs' only justification for the discovery is attorney argument that Amgen somehow [redacted]. While Plaintiffs cite no grounds for this false claim[5], even if Plaintiffs had a legitimate basis for their allegation, it would not justify the overly broad scope of a request for any and all instances in which Amgen has used [redacted].

[5] [redacted]

Respectfully,

/s/ Melanie K. Sharp

Melanie K. Sharp (No. 2501)

MKS:

cc: Michael P. Kelly, Esquire (by e-mail)
Daniel M. Silver, Esquire (by e-mail)